

REMARKS/ARGUMENTS

The above-identified patent application has been reviewed in light of the Examiner's Action dated June 18, 2003. No claims have been amended or canceled by this Response. Therefore, Claims 1-9 are pending. As set out more fully below, reconsideration and withdrawal of the rejections of the claims are respectfully requested.

Claims 1-3 and 5 stand rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. Applicants respectfully traverse this rejection. Claims 1-3 and 5 are directed to a method for tracking samples of a clinical study. In particular, by performing the recited steps of the method, information regarding samples taken as part of a clinical study is collected in a database. Furthermore, the particular steps of the method facilitate the efficient and accurate performance of steps included as part of a clinical study protocol. A clinical study protocol will necessarily include laboratory procedures conducted on samples from a patient, such as determining the genotype of a patient. Accordingly, the method recited in Claim 1 is a useful process, and therefore is statutory subject matter. Reconsideration and withdrawal of the rejections of Claims 1-3 and 5 as being directed to non-statutory subject matter is requested.

Claims 1-3, 5-6 and 8 stand rejected under 35 U.S.C. §102 as being anticipated by U.S. Patent No. 5,675,745 to Oku et al. ("Oku"). In order for rejection under 35 U.S.C. §102 to be proper, each and every element as set forth in a claim must be found, either expressly or inherently described, in a single prior art reference (MPEP §2131). However, each and every element of the rejected claims cannot be found in Oku. Therefore, reconsideration and withdrawal of the rejections of Claims 1-3, 5-6 and 8 are respectfully requested.

Claim 1 is generally directed to a method for tracking samples of a clinical study. According to the method, a first clinical study protocol comprising a plurality of procedures, wherein said procedures comprise steps, is defined. Samples for the first clinical study protocol are accessioned by recording in a database identifying information for the samples and identification of the first clinical study. A work list is created by assigning a particular scientist to perform a particular procedure on particular samples. A check list comprising steps of the at least one procedure to be performed on the samples of a work list is created, and the steps of the check list are performed. Completion and results of at least a portion of the steps are recorded on the check list.

Claim 6 is generally directed to a computer implemented method for tracking samples of a clinical study. According to Claim 6, a computer having an associated memory is provided. In addition, a list of standard operating procedures comprising procedure steps is provided, as is a list of samples. The list of standard operating procedures is merged with the list of samples to generate a check list for use in connection with the clinical study, wherein the list of standard operating procedures, the list of samples and the check list are all stored in the computer memory.

Claim 8 is generally directed to a computer implemented method for tracking samples of a clinical study. According to Claim 8, a plurality of samples is accessioned, and identifying information is stored in a provided computer. Claim 8 also recites determining procedures to be taken with respect to the samples, wherein the procedures comprise a plurality of steps. At least a first work group comprising at least a first of the plurality of samples is defined, the first work group comprising at least one procedure. The work group is stored in the computer. At least one check list comprising the at least first work group and the steps comprising at least one procedure is

prepared and stored in the computer. Claim 8 also recites performing the steps and recording performance of the steps in the computer.

The Oku reference is generally directed to a method for organizing work flow using a database. (Oku, Col. 1, ll. 16-29). More particularly, Oku discusses a system for managing work flow. (Oku, Col. 23, ll. 45-50). As part of the system, Oku allows various high level time tables associated with clinical studies to be viewed. (Oku, Col. 22, ll. 30-36). In addition, standards of operation concerning a clinical trial plan can be displayed. (Oku, Col. 22, ll. 37-44). However, Oku does not disclose a method for tracking samples of a clinical study as claimed. For example, Oku does not discuss accessioning samples by recording in a database identifying information for the samples. In addition, Oku does not discuss creating a checklist comprising steps, and recording in the database completion and results of at least a portion of the steps on the checklist. Therefore, the rejections of Claims 1, 6, and 8, and of Claims 2, 3, 5, which depend from Claim 1, should be reconsidered and withdrawn. To the extent that the Examiner believes Oku makes such a disclosure, the Examiner is requested to provide specific references as to where such disclosure in Oku can be found.

Claims 4, 7 and 9, which depend from Claims 1, 6 and 8, respectively, stand rejected under 35 U.S.C. §103 as being obvious over Oku in view of an article by Evans and Relling ("Evans"). Evans is generally directed to describing the use of pharmacogenomic studies in connection with drug development. Even if the proposed combination of Evans and Oku is proper, the Evans article does not supply the elements of the invention of Claims 1, 6 and 8 noted above that are not present in Oku. For example, Evans does not disclose creating a check list and recording completion of

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steps on the checklist. In addition, the Office Action does not make a showing of any teaching, motivation or suggestion to combine the Evans and Oku references. In the absence of such a showing, the proposed combination of references is improper and should be reconsidered and withdrawn. Accordingly, for at least these reasons, the rejections of Claims 4, 7 and 9 as obvious should be reconsidered and withdrawn.

The application now appearing to be in form for allowance, early notification of same is respectfully requested. The Examiner is invited to contact the undersigned by telephone if doing so would expedite the resolution of this case.

Respectfully submitted,

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